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EXAMINER	
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ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
06/24/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/585,722	LAITENBERGER ET AL.	
	Examiner	Art Unit	
	JACQUELINE WOZNICKI	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,7,9-24,26,27 and 34-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,7,9-24,26,27 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/17/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-4, 6-7, 9-24, 26-27, and 34-36 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2-4, 9, 11, 14, 26-27, 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite for referring to "strut loop portions" when claim 1, from which it depends, also refers to "strut loop portions". Therefore, it is not clear whether these refer to different strut loop portions or the same. Clarification is required.

Claim 3 is indefinite for claiming "said two loop portions" when there is improper antecedent basis for this in the claims. It is not clear whether this refers to a plurality of the "strut loop portions" or something else.

Claim 9 is indefinite for referring to "the other" when there is improper antecedent basis for this in the claim.

Claim 11 is indefinite for referring to "loop portions" when it is not clear whether this refers to said "strut loop portions" in claim 1 or to something else.

Claim 14 is indefinite for referring to "spaced loop portions". It is not clear whether this refers to the "strut loop portions" from claim 1 or something else.

Claims 16-17 are indefinite for referring to "the cooperating portions" when the claim from which is depends appears to define "cooperating *link* portions".

Claim 35 is indefinite for referring to "a periphery of a string of equal area strut lobes". It is not clear what this is.

Claims 4 and 36 are indefinite for depending on an indefinite claims.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "periphery of a string of equal area strut lobes" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

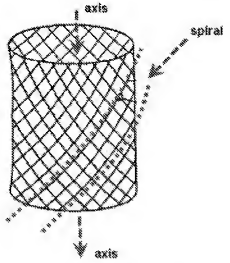
Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 11-14, 26-27, and 34-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Gray et al. (US 20050049683 A1), hereinafter known as Gray.



Annotated Figure 10

Regarding **claim 1**, Gray discloses an implant comprising:

a tubular metal stent (Figure 3 (tubular); Abstract (metal); [0018] (stent)) defining a lumen centered on a central longitudinal axis (Annotated Figure 10; "axis"), the stent being radially expansible from a radially compact delivery configuration to a radially larger deployed configuration ([0114]),

a plurality of electrically-conductive closed loops comprising struts forming an apertured wall of the stent (Figure 3, items 132, 134, 136, 138 (loops) and [0095]; the curved segment loops form the meshed wall of the stent. The struts are the "strands", Figure 10 item 221.),

each of said loops being formed from strut loop portions (Figure 1, items 102, 104) providing electrically-conductive current pathways within which eddy currents are liable to be induced when subjected to a time-dependent external magnetic field (Figure 1, item 110, 112), each of said loops including a first current pathway and a second current pathway ([0076]) wherein said first current pathway and said second current pathway are arranged such that, regardless of the direction of said external magnetic field, the direction of the eddy current that would be induced by said field in said second current pathway is the reverse of the direction of the eddy current that would simultaneously be induced by said field in said first current pathway, thereby to prevent flow of eddy currents in each of said loops, thereby mitigating a Faraday Cage effect and rendering the lumen visible to MRI (Abstract).

Regarding **claim 2**, Gray further discloses each of said loops having a strut loop portion formed as a first lobe (Figure 2, item 126) and a second lobe (Figure 2, item 128) of a figure of eight, further comprising a cross-over point (Figure 2, item 124) between the first and second lobe.

Regarding **claim 3**, Gray discloses the implant of claim 2, further comprising an electrically-insulating joint between said two loop portions at the cross-over point ([0077]).

Regarding **claim 4**, Gray discloses the implant of claim 2 wherein each of the loops have additional lobes and additional cross-over points between additional lobes, with the areas bounded by the lobes being such that in aggregate, the area bounding by one set of lobes equals the area bounded by a cancelling remainder of the lobes (Figures 3-6 show multiple loops, lobes, and cross-over points. Also, see [0077]).

Regarding **claim 11**, Gray further discloses wherein loop portions correspond to struts that are joined end-to-end to each other (Figure 5) and can deploy in use to form a zig zag pattern ([0085]; zig zag).

Regarding **claim 12**, Gray further discloses the plurality of loops arranged mutually axially adjacent and spaced along the axis (Figures 3-6).

Regarding **claim 13**, Gray discloses the implant of claim 12 wherein adjacent loops are connected to each other by electrically insulating links (Figure 5, item 179; [0087]).

Regarding **claim 14**, Gray further discloses each of the loops including a plurality of electrically insulating links that connect spaced loop portions of the loop (Figure 5, item 179; [0087]).

Regarding **claims 26-27**, Gray further discloses the implant being made of Nitinol or stainless steel (Abstract).

Regarding **claim 34**, Gray further discloses each closed loop exhibits lobes (Figure 2, item 126, 128 (and Figure 6)) with an equal lobe area on opposite sides of the stent ([0077], [0094]).

Regarding **claim 35**, Gray discloses an implant comprising:

a tubular metal stent (Figure 3 (tubular); Abstract (metal); [0018] (stent)) defining a lumen centered on a central longitudinal axis (Annotated Figure 10, "axis"), the stent being radially expansible from a radially compact delivery configuration to a radially larger deployed configuration ([0114]),

the stent comprising an electrical conductor ([0077]; "conductive rings") having a plurality of closed loops (Figure 2, items 126 and 128) comprising struts (Figure 10 item 221 "strands") electrically insulated from each other ([0079]), each of the closed loops having a periphery of a string of equal area strut lobes within said closed loop (Figures 3-6; [0077]), and every one of the strut lobes having a counterpart strut lobe located diametrically opposite on the stent (Figure 6 and [0094]; the lobes inherently have diametrically opposed "counterpart strut lobes" or artifacts would be present), the electrical conductor mitigating a Faraday Cage effect to permit imaging of the lumen by MRI (Abstract).

Regarding **claim 36**, Gray further discloses each of the closed loops include an even number of strut lobes ([0081], [0085]; even number of loops).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-7 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray as applied above to claim 1 in view of Bucker (WO 03015662 A1; US 20040249440 A11 is being used as a translation thereof).

Regarding **claim 6-7 and 9-10**, Gray discloses each of the loops wrapping around an axis in the form of a spiral (Annotated Figure 10), wherein each of the loops wraps around the axis in a path that spirals around the axis from one end of the implant to the other (Annotated Figure 10), but fails to disclose the loops wrapping with an integral whole number of turns, the number of turns being at least three, and the pitch of the spiral being constant.

However, regarding **claims 6-7 and 9-10**, Bucker teaches strut loops wrapping around an axis with an integral number of whole turns (Figure 4a), and at least three turns (Figure 4a shows four turns), and the pitch of the spiral being constant (Figure 4A). Gray and Bucker are involved in the same field of endeavor, namely stents. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent of Gray by having at least three turns as is taught by Bucker in order to have a stent that is long enough to cover a diseased area and prevent restenosis an entirety of a problem area. Although dependant on the implantation site and the amount of diseased vasculature, the number of turns would be able to be optimized to correspond to the length of the stent needed. Further, it would have been obvious to have the pitch of the spiral path be constant in order to simplify the manufacturing process. By not changing the pitch of the spiral, the process of manufacture will take less

time and be simpler, since calculations and modifications would not have to be made to change the pitch.

Claims 15-16, 18-19, 21, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray as applied above to claim 1 in view of Blank (WO 03/075797 A2).

Regarding **claims 15-16, 18-19, 21, and 23-24**, Gray discloses the invention substantially as claimed but fails to disclose the links being mechanical couplings movable to each other, with a hook and an eye, a layer of ceramic or adhesive bonding material, the couplings being interlocking fingers, mechanically engaging surfaces, having an overlying restraining strap, a molded connector piece, or a thinned portion.

However, regarding **claims 15-16, 18-19, 21, and 23-24,** Blank teaches a stent visible in MRI with electrically insulating mechanical couplings (Figure 5), with a first cooperating link portion (Figure 5, item 32) and a second cooperating link portion (Figure 5, item 34),

wherein the cooperating portions can move relative to each other ([0072]),

wherein including a layer of bonding material between the cooperating link portions ([0071]; the pin (Figure 4, item 26) comprises the "bonding material" because it is located between the cooperating link portions, bonds the two portions together, and has at least one layer of a material)

wherein the bonding material is ceramic ([0071]; the pin may be ceramic),

wherein the mechanical coupling comprises interlocking fingers (Figure 4, item 22 and 24),

wherein each link includes a molded connector piece (Figure 4, [0071]; a pin is a molded connector piece).

wherein each link includes a portion that is locally thinned with respect to the thickness of the wall implant (Figure 5; portions 32 and 34 are at least about half the thickness of the wall implant).

Gray and Blank are involved in the same field of endeavor, namely stents. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent of Gray by using the mechanical couplings as taught by Blank in order to have a variety of connectors for the stent struts of Gray. This way, the degree of flexibility of the stent and mobility of struts relative to one another can be controlled, and a more flexible stent will result. This will allow the stent to be implanted in a variety of vessels, for example, very tortuous vessels that require a stent that is flexible.

Claims 15, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray as applied above to claim 1 in view of Pacetti (US 6712844 B2)

Regarding **claims 15, 18, and 20**, Gray discloses the invention substantially as claimed with an electrically insulating material connecting link portions (Figure 11, item 234), but fails to disclose a layer of adhesive bonding material or ceramic bonding material between the cooperating link portions.

However, Pacetti discloses mechanical coupling linkage (Figure 8, Column 8 lines 7-9) with a layer of bonding material between the cooperating link portions in the form of an adhesive (Column 7, lines 2-13; adhesive), or a layer of ceramic (Column 7, lines 38-39).

Gray and Pacetti are involved in the same field of endeavor, namely stents. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent of Gray by using the mechanical connections as taught by Pacetti because they are recognized alternatives in the art as strut connectors. Using the specific adhesive or ceramic bonding materials as taught by Pacetti would further be obvious to ensure complete biocompatibility and the ability to hold the portions together even under body conditions, ensuring the stent remains together in place as long as needed without coming apart.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gray as applied above to claim 1 in view of Raulerson (US 5599311 A).

Regarding **claim 17**, Gray discloses invention substantially as claimed but fails to disclose a hook and eye portion holding mechanical linkages together.

However, regarding **claim 17**, Raulerson teaches two cooperating portions of a stent being held together by a hook and eye (Column 7, lines 35-41; Velcro). Gray and Raulerson are involved in the same field of endeavor, namely stents. It would have been obvious to one of ordinary skill in the art at the time

the invention was made to modify the stent of Gray by using a hook-and-eye closure for connecting links as is taught by Raulerson in order to increase the flexibility of the stent at every connection point. Velcro (hook-and-eye connections) allow movement relative to each side, and so the flexibility of the stent will increase, allowing the stent to be implanted in a variety of tortuous vessel with ease.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gray in view of Blank as applied above to claim 15, and further in view of Lenker et al. (US 6176875 B1), hereinafter known as Lenker.

Regarding **claim 22**, Gray discloses the invention substantially as claimed but fails to disclose mechanically engaging surfaces in combination with at least one restraining strap. However, regarding **claim 22**, Blank teaches mechanical coupling comprises mechanically-engaging surfaces (Figure 5) and Lenker teaches at least one restraining strap overlying strut link portions (Figure 5c, item 102).

Gray, Blank, and Lenker are involved in the same field of endeavor, namely stents. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent of Gray in view of the mechanically engaging surfaces as taught by Blank in order to be able to control the degree of flexibility of the stent. By having the connections of Blank, a more

flexible stent will result, allowing the stent to be implanted in a variety of vessels, for example, very tortuous vessels that require a stent that is flexible.

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the restraining strap as taught by Lenker in order to restrain the stent until ready for expansion.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE WOZNICKI whose telephone number is (571)270-5603. The examiner can normally be reached on M-R, 10 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571)272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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06/08/11